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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/214,155	12/29/1998	HIROAKI TAKAYAMA	Q52816	5866

7590 04/20/2004

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WASHINGTON, DC 200373202

EXAMINER

QAZI, SABIHA NAIM

ART UNIT PAPER NUMBER

1616

DATE MAILED: 04/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

### Application No.

09/214,155

### Applicant(s)

TAKAYAMA ET AL.

### Examiner

Sabiha N. Qazi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on 1/2/04.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☐ Claim(s) 3 and 4 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 3 and 4 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

***Final Office Action***

Acknowledgement is made of the response filed on 12/22/03. This application is a 371 of PCT/JP98/01979 filed on 4/30/98. Claims 3 and 4 are pending. No claim is allowed.

The application 09/959,541 has been filed under 35 USC 371 as a national stage application of PCT/ JP99/ 05778. JP 99/5778, published November 9, 2000, is applicant's own international publication. Double Patenting rejection was made for the same reasons. The rejection over 09/959,541 is withdrawn because the application is abandoned. Double Patenting rejection over 10/069481 is maintained for the same reasons as set forth in our previous office action.

Applicant arguments were fully considered but are not found persuasive therefore, rejection is maintained. The argument that "a minimum, the examiner is respectfully requested to hold this provisional obviousness -type double patenting rejection in abeyance until a decision on non-patentability is made in the cited application", is not justified.

Presently claimed invention is drawn to 2-substituted vitamin D<sub>3</sub> compounds, their composition and method of use.

Declarations were fully considered where applicants are explaining the date of the invention prior to the reference cited for the rejections. When claims will be considered allowable for other issues the application may be send to board of interference to make a final decision regarding priority of the presently claimed invention and the prior art DeLuca et al. (US 5,945,410) and (US 6,306,844). Claim 3 rejected stand 35 U.S.C. 103(a) as being unpatentable over DeLuca et al. (US 5,945,410) and (US 6,306,844). Both the references teach 2-methyl and 2-alkyl 19-nor 20(S) vitamin D<sub>3</sub>. See the entire documents especially fig. 1 and 2 and

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examples 1; lines 36-67, in col. 15 and lines 1-37 in col. 16 in '410; formula 1 and lines 1-19 and 45-67, col. 2; see also cols. 5, 6 and Table 1 in US '844.

Claim 4 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Trost M. Barry et al. The reference teaches a palladium-catalyzed alkylative cyclization of enynes for the synthesis of vitamin D derivatives for the same reasons set forth in our previous office actions.

The instant claims differ from the reference by employing an analogous starting material which differs in having a methyl group at 4-position of the compound of formula III i.e. in instant claims 4-position is substituted by a methyl group whereas prior art teaches no substituents at this position.

The starting materials are analogous in that they are both belong to enynes of formula III.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper time wise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 3 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 7 and 8 of co pending Application No. 10/069481. Although the conflicting claims are not identical, they are not patentably distinct

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from each other because 2-position of vitamin D represents lower alkyl group and it is claimed in 10/069,481. In 10/069,481 vitamin D3 is 2-substituted alkyl. In all the above copending applications and presently claimed invention 2-substituted vitamin D3 compounds are claimed which are considered obvious over the other.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

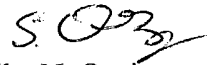
***Telephonic Inquiry***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha N. Qazi whose telephone number is (571) 272-0622. The examiner can normally be reached on any business day.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Sabiha N. Qazi  
Primary Examiner  
Art Unit 1616

4/16/04  
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